Queensland

Genome Editing Technology Research and Usage Youth Act 2018

Youth Act No. 5 of 2018

A Youth Act to allow and regulate the research of, and treatment using CRISPR/CAS9 Genome editing technology in Queensland

[Assented to 26 October 2018]

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Contents

The Parliament of Queensland enacts—

Part 1 Preliminary

1 Short title

This Youth Act may be cited as the *Genome Editing Technology Research and Usage Youth Act 2018*.

2 Commencement

This Youth Act commences on a day to be fixed by proclamation.

3 Main purpose of Youth Act

The main purpose of this Youth Act is to provide treatment for otherwise incurable genetic disorders through the use of CRISPR technology. To allow this, this Act legislates for the ethical research, development and use of CRISPR in the public system.

4 Definitions

In this Youth Act—

animal means any non-human organism belonging to the Animalia kingdom.

CRISPR means the genetic engineering tool that uses a CRISPR sequence of DNA and its associated protein to edit the base pairs of a gene. CRISPR also refers to the acronym Clustered Regularly Interspaced Short Palindromic Repeats.

continuing means further experimentation on a test subject

Cosmetic modifications means direct aesthetic modifications of the body to affect physical appearance.

ex vitro means experimentation or measurements done in or on tissue from an organism in an external environment with minimal alteration of natural conditions.

gene therapy means the introduction of correct foreign genetic material into a cell for the purpose of alleviating a genetic disorder.

genetically inherited diseases means a disease that is caused by a fault in DNA, a disorder inherited from the DNA of an individual's parents. Such diseases usually originate from a mutation in the DNA.

germline editing means genetic modifications made in an embryo, that develops into a child. Hence, an irreversible alteration changes the genetics of any decedents or offspring.

in vitro means performed or taking place in a test tube, culture dish, or elsewhere outside a living organism minor means a person under the age of 18.

somatic cells means all cells present in the body except the gametes germ cells i.e. oocytes and spermatocytes

somatic gene editing means genetic modifications made in the somatic cells of an individual, not in their gametes, hence they are not heritable by their descendants

Part 2 Legalising Research into CRISPR Technology

5 Research Right

(a) Research must be limited to the public sector until such a time that the Genome Editing Parliamentary Committee deem it safe and appropriate for the curing of genetic disorders.

(b) Once the technology is deemed to have progressed enough to allow private access, it will be allowed for only several set uses for curing genetic disorders and cosmetic uses

(c) Under no circumstances can the technology be used for the alteration of body parts

(d) Private corporations will have to apply for licensing to begin private use

(e) approval and period inspections are defined in Part 3;

(f) the organization must pass periodic inspections that may occur at any time without any prior warning;

(i) failure to pass period inspections will result in immediate termination of research rights and a handover of current findings to The National Health and Medical Research Council.

6 Research Restrictions

(1) Research conducted must be somatic by definition

(a) The Genome Editing Parliamentary Committee will be formed on the basis of a drafted proposal into Parliament to further investigate whether research standards have progressed to allow further privatisation.

(b) This will be a committee formed on a multi-partisan basis consistent with other investigatory Parliamentary committees and

will consult with a subcommittee made up of a balance between current researchers and prospective industry leaders.

(c) After the initial decision on when to privatise, the committee will draft a set standard on the areas believed to progress and the needed standards to apply for a licence to research or develop and sell products/services.

(d) All research and future uses conducted will adhere to directions set in the research until licensing directions and standards are set by the Genome Editing Parliamentary Committee.

(e) Licences will be provided for research on the basis that they meet standards set by the committee

(f) The committee will further meet annually to amend the standard as per research developments over the year and to approve or revoke licences to research or develop and sell products or services.

(g) Any violations of set standards or other Queensland law in practice means automatic revocation of the licence and the committee holds power to revoke all licences at any time.

(h) Under no circumstances should the standards allow CRISPR research and practice be allowed in germline editing

(i) Misuse of rights around any section of the standard will result in the immediate revoking of a licence and an investigation into the incident.

(2) Subject to the discretion of The National Health and Medical Research Council, approval on an individual basis, only —

(a) Female carriers of a test subject (foetus) over the age of 18 to be eligible for testing;

(b) The carrier of the foetus must have provided written consent that is legally binding and agreed to the contract outlining that HIIRO and research facilities undertaking experiments are not liable for any damages brought forward by the tested foetus;

(c) The carrier must be fit for testing as assessed and approved by a practicing doctor to ensure the safety of the applicants involved;

(d) Personal information must be provided to The National Health and Medical Research Council;

(e) In the circumstances of an organisation's right to research being terminated or suspended, the organisation is legally obligated to ensure that individual contracts are not breached;

(f) In the circumstance of an individual under the age of 18 being used as a test subject, the organisation is subject to a thorough investigation.

7 Confidentiality

(1) Information collected is on the basis that—

(a) it is necessary for the organisation to collect the family, social or medical history of an individual (the patient) to provide a health service to the patient; and

(b) The health information about the third party is part of the family, social or medical history necessary for the organisation to provide the health service to the patient; and

(c) the health information is collected by the organisation from the patient consensually or, if the patient is physically or legally incapable of giving the information, a responsible person for the patient.

(2) A research facility can disclose information if—

(a) the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety; and

(b) it is impracticable for the organisation to obtain the individual's consent to the use or disclosure; and

(c) in the case of disclosure—the organisation reasonably believes that the recipient of the information will not disclose the information, or personal information derived from that information.

(d) the organisation has obtained the information in the course of providing a health service to the first individual; and

(e) the organisation reasonably believes that the use or disclosure is necessary to lessen or prevent a serious threat to the life, health or safety of another individual who is a genetic relative of the first individual

(3) A person can disclose information in the course of carrying out duties or functions under this Act or under a corresponding State law by the following avenues —

(a) the Commonwealth; or

(b) a Commonwealth authority; or

(c) a State agency; or

(d) the Gene Technology Technical Advisory Committee; or

(e) an order of a court; or

(f) approved applicants requesting information

(4) Any breaches of this, will be dealt with via the Privacy Act 1988.

Part 3 Research conditions

8 Animal Welfare

(1) Activities involving the experimental research carried out on any animalia/animals must be submitted to;

(a) The Formative Genome Research Committee(FGRC); or

(b) Approved by already existing and government approved medical and research facilities that specialise in the treatment and medical experimentation of animal life.

(2) The Formative Genome Research Committee (FGRC) must include the following

(a) Must be considered a subcommittee to that of the National Health and Medical Research Council (NHMRC); and

(b) Reviewed by the NHMRC every second year

(c) All members may be voted in by existing members of the council but can only be approved and appointed by NHMRC, these members can

(d) Be comprised of at least 9 individuals of the following stature

(e) At minimum five individuals whom have a minimum of approximately 15 years' experience in the medical or scientific field, more so relating to the areas of gene and DNA research;

(f) At least one community representative individual who has held/currently holds a parliamentary seat in either local, state or federal government;

(g) At minimum two individual whom represents a majority religious ideology, a member of majority religion, with localised power within the religion specified;

(h) At minimum one individual who represents the private sector of either medicine or medical research, must have a 6 year minimum experience within the field of gene editing and DNA research;

(i) All members of FGRC will be financially subsidised by the government and in accordance of NHMRC;

(j) No member may sit for a period over seven years, unless;

(k) Reviewed by the governing NHMRC body, or;

(l) Reapplies after a year apart from the FGRC

(3) The FGRC will have the rights and obligation to make decisions pertaining to—

(a) The accreditation and approval necessary for both government and private sector organisations to carry out the relevant gene editing experimentation and testing

(b) May also direct and help in the approval for government funded grants to be handed down for both government run and private sector organisations, although all formal grants must be approved by NHMR

(c) Will have the authority to stop experimentation process at any time necessary at any given research facility

(d) Must conduct monthly reviews on all approved gene editing research and experimentation projects

(e) May work as to provide both a moral/ethical and scientific guide to all research facilities

(4) All institutions, within private and public sector must adhere to the following guidelines within the research rights to animal testing and formative experimentation as described by the FGRC, evaluations must be made;

(a) The evaluations will be reviewed quarterly, every three months, and should

(b) Reviewed monthly by relative inner organisation panels and/or;

(c) Research heads of department

(5) Animal types and research guidelines include;

(a) All animals must be treated and used in accordance to the National Health and Medical Research Council Act 1992 Section 32;

(b) All animals used must be first approved by the FGRC

(c) No animals that do not adhere to current Australian law in regard to animal species will be approved or considered

(d) The penalty for breaking any given animal welfare restrictions in the case of an individual will be imprisonment for a minimum of 2 years and/or 150 penalty points, corporations at the hand of the same breach will;

(e) Be charged triple the penalty points given to any one individual for every breach and will be disqualified from researching within the gene editing sphere.

9 Assurances

(1) All assurances determine the adequacy of the institution's proposed research including—

(a) the care and use of animals;

(b) advancement of research.

(2) HIIRO may disapprove the Assurance preventing the

(a) The commencement of the research

(b) Without an approved Assurance no CRISPR technologies can be researched.

(3) FGRC may approve the Assurance resulting in the research commencing

(a) the approval will be for a specified period of time no longer than 3 months.

(4) The Assurance must contain the following—

(a) a list of every branch and major component of the institution; and

(b) the lines of authority for administering the program; and

(c) the qualifications, authority, and responsibility of the veterinarians who will participate in the program and the scope of their participation; and

(d) the health program for personnel who work in the laboratory facilities or have frequent contact with animals; and

(e) a synopsis of training or instruction in the humane practice of animal care and use, as well as training or instruction in research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress, offered to scientists, animal technicians, and other personnel involved in animal care and treatment; and

(f) the gross square footage of each animal, the species housed therein, and the average daily inventory, by species, of animals in each facility; and

(g) Any other information requested by HIIRO.

(5) A reporting system every week must be instituted between the FGRC board and research facilities that includes updates on —

(a) the progression of technology

(b) health and reactions of subjects in testing

(c) full details of results of tests and/or exercises and/or experiments

(6) Reports must be in-depth and explain every practice being made by the research facility. Warnings will be given to the research facility if

(a) information in reports are inadequate

(b) reports are not made and given to HIIRO within the time specified

(c) reports indicate a misdemeanour

(d) if the research facility has received 3 warnings within 1 year, they must be held accountable to court to determine the survival of the facility and if they are fit to continue.

(7) HIIRO must have a sufficient number of members to police such a demanding load of medical research and be split into

(a) president

(b) Secretary

(c) Treasure

(d) a team consisting of—

(i) Scientists

(ii) policy makers

(iii) planners

(iv) advisors.

10 Phases of clinical research

(1) Each phrase must be completed to a regulatory approved standard, assessed by HIIRO before continuing research—

(a) Phases 1: theoretical analysis and theoretical experimentation must be completed to an exemplary standard dictated by the HIIRO;

(b) Phase 2: animal Testing must be completed on Animal Type 1 (See Section 2 clause c) exemplary standard set by the HIIRO;

(c) Phase 3: animal Testing must be completed on Animal Type 2 (See Section 2 clause d) to an exemplary standard regulated by the HIIRO

(d) Phase 4: testing on a select study of humans carrying extremely fatal diseases must be undertaken with HIIRO's regulation;

(i) all participants will have to apply and be approved by HIIRO; all participants must be of sound mind and independence

(e) Phase 5: testing on a wider selection of humans carrying extremely fatal diseases must be undertaken with HIIRO's regulation.

(i) must comply with previous stated conditions

(f) Phase 6: testing on a large group of fatally ill humans may commence with HIIRO's regulation.

(i) must comply with previous stated conditions

(g) Phase 7: The treatment will be made available to public hospitals in compliance with part 5

Part 4 Application of CRISPR

11 Access and Availability of the treatment

(1) Access to the treatment

(a) An unborn child must have first been researched and referred by a qualified doctor.

(b) If the child, after research, is found to have a certainty of death in the future, the child will be allowed to receive the treatments.

(i) If the child is not found to have any signs of imminent death in the future, it will not be submitted to this treatment.

(2) Treatment only available from public hospitals only—

(a) A public hospital, owned and ran by the government, will have full access to the treatment.

(b) The public must pass inspections and have experienced doctors in employment prior to instalment of the treatment within the facility.

(c) Failure of the inspection will result in improvements needed to be made to the facility before qualification to offer this treatment.

Part 5 Conditions for use of Crispr

12 Scope

(1) Permissible Applications

(a) CRISPR Technologies may be used for the purpose of somatic gene editing therapies for the treatment of Genetically Inherited Diseases, upon the following conditions—

(i) The gene therapy must have undergone successful human trials and be approved by the relevant legislative boards, as per section 3.

(ii) All gene therapies must occur in the context of a licensed medical processional and be approved by the relevant legislative boards.

(iii) The genetic editing occurring must be a registered genetic therapy.

(iv) Genetic treatment may occur at all places that are licensed by the Queensland Government as per the terms of this Bill. Further to this, CRISPR may also be used for diseases that

are not life threatening provided that successful human clinical trials have been provided for.

(2) Treatment Guidelines

(a) The use of CRISPR as a medical treatment is subject to the following guidelines—

(i) The gene therapy may occur both invitro and ex vitro.

(ii) Genetic therapies may be subsidized by the government

(iii) Registering it as life threatening in relation to wait times?

(iv) Consent must be given for this treatment, as is standard medical procedure.

(v) If the recipient of the treatment is under the age of 18, their parent or legal guardian must give consent on their behalf.

Part 6 Protocol in case of harmful dispositions present that do not qualify for CRISPR treatment

13 Protocol for cases

(1) In cases of physical and mental disability in subject—

(a) in cases where the foetus displays physical disability; or

(b) in cases where there is sufficient evidence to prove the foetus could grow to display mental disability; or

(c) is determined by a medical professional to be disabled; and does not qualify for treatment from CRISPR (part 5);

(d) the genetic and medical information will be secured and disclosed to the relevant disability services.

(2) In cases of genetic dispositions in a foetus to harmful and self-destructive behaviour in the future

(a) In cases where the subjects are undeniably genetically disposed too—

(i) Addiction; or

(ii) violence; or

(iii) depression; or

(iv) is deemed by a medical professional to have a disposition to harmful and self-destructive behaviour

(b) the relevant genetic and medical information will be disclosed to the relevant private institutions so that the risk and effects of these

behaviours and mental illnesses can be minimised and this information is to be shared and viewed only by medical professionals on a need to know basis.

(i) To share this information with non-medical professionals other than the parent/s or guardian/s of the foetus/child or;

(ii) To share or view this information under non-necessary circumstances will constitute malpractice.

(c) The parent/s or guardian/s will be given relevant information by a medical professional about how to minimise the risk and damage of these behaviours, if the subject is a minor or currently under the care of another

(3) In cases where the subject genetic dispositions are deemed harmful to the foetus's general health

(a) And do not qualify for treatment from CRISPR (part 5)

(i) The parents of guardians will be notified about these 24 dispositions and how to minimize their risk and effects by a medical profession, if the subject is a minor or currently under the care of another and;

(ii) The relevant government authorities will be notified as too these dispositions so the risk and damage of these dispositions might be minimized.